

FEB 10 2004

## Section 3

### 510(k) Summary

#### General information

The general information for the MammoSite RTS is included in the table below:

<b>Submitters name and address:</b>	Proxima Therapeutics, Inc. 2555 Marconi Drive, Suite 220 Alpharetta, Georgia 30005
<b>Submitters phone and fax numbers:</b>	Telephone: (770) 753-4848 Fax: (770) 753-4937
<b>Name of contact person:</b>	Martine D. Schneider <i>Manager, Regulatory Affairs &amp; Quality Assurance</i>
<b>Trade name:</b>	MammoSite Radiation Therapy System (RTS)
<b>Common name:</b>	Remote-controlled radionuclide applicator system
<b>Classification name:</b>	System, applicator, radionuclide, remote-controlled (per 21 CFR 892.5700)
<b>Date summary was prepared:</b>	July 2, 2002

#### Predicate devices

The ellipsoid MammoSite RTS devices are substantially equivalent to the following legally marketed medical devices in terms of its technical specification, intended use, and method of application:

Name	Manufacturer	510(k) Number
MammoSite Radiation Therapy System (RTS)	Proxima Therapeutics, Inc.	K011690
MammoSite RTS – 5-6 cm Spherical	Proxima Therapeutics, Inc.	K030558
Afterloading Applicators	Nucletron Corp.	K853912, K983341

#### Indications for use

The MammoSite RTS is an applicator intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

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## 510(k) Summary, Continued

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**Device  
description**

The MammoSite RTS is a radiation therapy system that includes the MammoSite RTS Catheter Tray and the MammoSite HDR Afterloader Accessories Tray. The MammoSite RTS Catheter Tray includes the MammoSite catheter and accessories to assist with the implantation of the catheter. The MammoSite is a catheter shaft with an inflatable balloon mounted on its distal end that positions the radiation source within the resected cavity for radiation delivery. The MammoSite Afterloader Accessories Tray contains the items needed to connect the afterloader to the MammoSite. Any device specifications that have changed as a result of the modifications to the device presented in this 510(k) have been documented in Proxima's product specifications for the MammoSite RTS.

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**Technological  
characteristics**

The MammoSite has the same intended use, similar technological characteristics, and similar materials/dimensions of the predicate MammoSite devices. The indication for use is the same as the predicate MammoSite RTS devices that are commercially available and is similar to other predicate devices. All MammoSite devices provide a means of delivering a radiation therapy in a tumor or tumor cavity. The MammoSite and brachytherapy applicators position the radioactive source for radiation therapy. The MammoSite and brachytherapy applicators utilize  $^{192}\text{Ir}$  seed or ribbon as the radiation source with similar dosimetric properties.

Any differences that exist between the ellipsoid MammoSite RTS and the predicate devices were discussed and shown that these differences do not affect safety or effectiveness. It was demonstrated that the ellipsoid MammoSite RTS is substantially equivalent to the predicate devices.

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## 510(k) Summary, Continued

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### Preclinical studies

Extensive pre-clinical studies were performed to support the ellipsoid devices presented in this 510(k). Preclinical studies conducted included in vitro laboratory studies to demonstrate that the ellipsoid MammoSite devices, the accessories and packaging, performed as intended under simulated use and challenge conditions. Biocompatibility testing was performed to demonstrate that the materials meet the biocompatibility requirements. The dosimetry of the MammoSite was characterized and is similar to the predicate MammoSite devices. Animal studies illustrate the performance of the device, and demonstrate a clinical dose of brachytherapy can successfully be delivered. Based on these findings, it was concluded that the ellipsoid MammoSite RTS could deliver an equivalent radiation dose to current commercially available brachytherapy applicators.

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### Clinical studies

The multi-center phase II clinical study initially done to evaluate the safety and effectiveness of the MammoSite RTS supports the ellipsoid devices presented in this 510(k). The clinical study included breast cancer patients who were undergoing tumor resection. Assessment methods used to evaluate safety and effectiveness included radiological and clinical measures. Brachytherapy was successfully delivered to the patients. A complete clinical summary including data analysis and individual patient data was provided to FDA in K011690. The clinical study demonstrated that the MammoSite RTS provides brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 10 2004

Ms. Martine D. Schneider  
Manager, Regulatory Affairs  
& Quality Assurance  
Proxima Therapeutics, Inc.  
2555 Marconi Drive, Suite 220  
ALPHARETTA GA 30005-2066

Re: K032067  
Trade/Device Name: Ellipsoid MammoSite®  
Radiation Therapy System  
Regulation Number: 21 CFR 892.5700  
Regulation Name: Remote controlled radio-  
nuclide applicator system  
Regulatory Class: II  
Product Code: 90 JAQ  
Dated: November 10, 2003  
Received: November 12, 2003

Dear Ms. Schneider:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050.

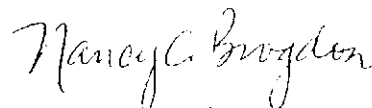
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Statement of Indications for Use

510(k) Number  
(if known) K032067

Device name MammoSite Radiation Therapy System (RTS)

Indications for  
use The MammoSite is intended to provide brachytherapy when the physician  
chooses to deliver intracavitary radiation to the surgical margins following  
lumpectomy for breast cancer.

*Prescription Use* ✓

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K032067